NIOX VERO® Airway Inflammation Monitor

User Manual

510(k) 133898

CE

Aerocrine

Remember
It is important to adhere to the following specified conditions:

- Ambient temperature: 50°F to 95°F
- Humidity: 20% to 80% RH (non-condensing)
- Mobile phones, cordless phones and gas emitting appliances might interfere with the instrument and should therefore be kept away from the instrument. Interference could make it impossible to perform a measurement.
- Normally a maximum of 10 measurements can be performed during continuous use. However, it is possible to perform 20 measurements in one hour if the instrument is paused for a minimum of 30 minutes prior to the next session of measurements.
- Avoid spilling water or other fluids on the instrument or Sensor.
- Always use a closed case or bag (NIOX VERO® bag recommended) for transportation and storage of NIOX VERO.
- It is recommended, after inserting a new sensor, to wait for three hours with the instrument switched on before performing a measurement.
- Operational life-time NIOX VERO® Instrument: Minimum 5 years at time of delivery, or 15, 000 measurements.
- Operational life-time NIOX VERO® Sensor: Maximum 12 months after opening package and installed in NIOX VERO or expiration date as stated on the Sensor, whichever comes first.

CAUTION!: Do not use NIOX VERO® in the proximity of areas where volatile substances such as organic fluids or disinfectants are being used. Special attention should be paid to aerosols and disinfection baths, either open vessels or ultrasonic baths.

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1 Important information

1.1 Before using NIOX VERO® Airway Inflammation Monitor

NIOX VERO® may only be operated as directed in this manual by trained healthcare professionals. Trained status is achieved only after careful reading of this manual. Read the entire instructions for use and make certain that you fully understand the safety information.

Symbol	Description
WARNING	Indicates a potentially hazardous situation that, if not avoided, can result in bodily harm or injury.
CAUTION	Indicates a potentially hazardous situation that, if not avoided, can damage a product or system, cause loss of data or harm to business.
Note	Alerts the reader to important information on the proper use of the product, user expectations, error situations, and actions related to these.

1.2 About this manual

NIOX VERO® User Manual - US 000190 (EPM-000165), version 04, May 2015, for instruments with software version 1D1x-xxxx. X can be any number between 0 and 9 or a character. For instructions on how to view the software version number installed in the instrument, see page 18.

Information in this document is subject to change. Amendments will be made by Aerocrine AB as they occur.

The User Manual provides instructions on how to operate NIOX VERO®. It contains numbered step-by-step instructions with screens and illustrations. Choices within steps are displayed with bullet points.

For clinical and performance characteristics, refer to the NIOX VERO® Labeling Summary/Package Insert 000249 (EPS-000069).

1.3 Compliance

NIOX VERO® is CE-marked according to In Vitro Diagnostics Device Directive 98/79/EC. NIOX VERO® is RoHS compliant.

1.4 Responsible manufacturer and contacts

Mailing address:
Aerocrine AB, P.O. Box 1024
SE-171 21 Solna, Sweden

Visiting address:
Råsundavägen 18
SE-169 67 Solna

www.aerocrine.com
www.niox.com

1.5 Warnings

- NIOX VERO® should only be operated by healthcare professionals.
- Operate NIOX VERO® as stated in this manual. Aerocrine accepts no responsibility for damaged equipment or faulty results, if the equipment is not handled according to this manual.
- When selecting an accessory for your NIOX VERO® product keep in mind that an accessory not recommended by Aerocrine may result in

loss of performance, damage to your NIOX VERO® product, fire, electric shock, injury or damage to other property. The product warranty does not cover product failure or damage resulting from use with non approved accessories. Aerocrine takes no responsibility for health and safety problems or other problems caused by the use of accessories not approved by Aerocrine.

- NIOX VERO® should not be used adjacent to or stacked with other equipment.
- Only use the power supply provided. Pull the plug when disconnecting NIOX VERO® from the power outlet.
- Use only the breathing handle supplied by Aerocrine.
- No modification of NIOX VERO® instrument, handle or Sensor is allowed.
- Do not drop the instrument or subject it to strong impact.
- Do not use a damaged NIOX VERO® instrument or damaged components.
- Keep the instrument and Sensor out of water. Ensure that no liquid is spilled or dropped on the instrument or Sensor.
- Do not heat or dispose of the instrument or Sensor in fire. Refer to “Disposal of instrument and accessories” on page 37.
- NIOX VERO® and the NO scrubber in the breathing handle contains potassium permanganate. Used or expired instruments and breathing handles should be disposed of as hazardous waste in accordance with local waste disposal regulations.
- The breathing handle must not be used after the expiration date.
- Patient filters should be used immediately after opening.
- NIOX VERO® Sensor contains chemicals that could be harmful if swallowed.
- Do not touch or clean the white Sensor membrane.
- Do not clean the sensor. Cleaning of the Sensor with ethanol or similar disinfectant might destabilize it for a non-predicable time period.
- After inserting a new Sensor it is recommended to wait for three hours with the instrument switched on before performing a measurement.
- Use of substances containing alcohol close to the NIOX VERO® instrument may cause erroneous measurement results.
- Do not reuse the patient filters.
- Do not use NIOX VERO® in the proximity of areas where volatile substances such as organic fluids or disinfectants are being used. Special attention should be paid to aerosols and disinfection baths, either open vessels or ultrasonic baths. Do not use the instrument in the presence of flammable anesthetic, vapors or liquids.

1.6 Indications for use

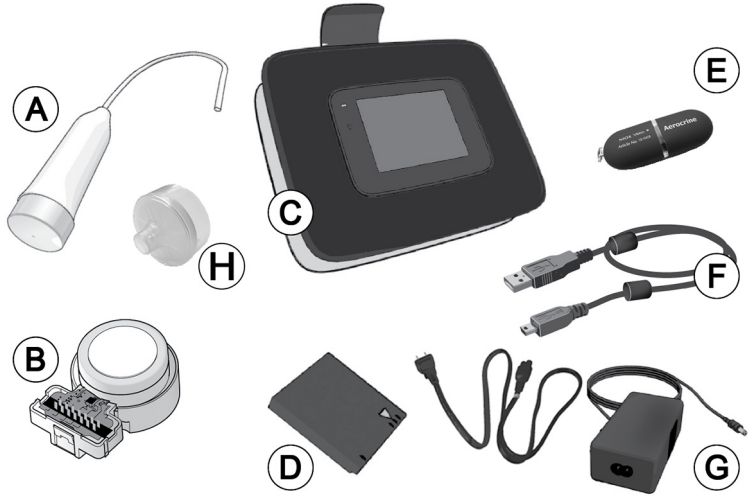
NIOX VERO® measures Nitric Oxide (NO) in human breath. Nitric Oxide is frequently increased in some inflammatory processes such as asthma. The fractional NO concentration in expired breath (FeNO), can be measured by NIOX VERO according to guidelines for NO measurement established by the American Thoracic Society.

Measurement of FeNO by NIOX VERO is a quantitative, non-invasive, simple and safe method to measure the decrease in FeNO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy, as an indication of the therapeutic effect in patients with elevated FeNO levels. NIOX VERO is suitable for children, approximately 7 - 17 years, and adults 18 years and older.

FeNO measurements provide the physician with means of evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to the established clinical and laboratory assessments in asthma. The NIOX VERO is intended for prescription use and should only be used as directed in the NIOX VERO User Manual by trained healthcare professionals. NIOX VERO cannot be used with infants or by children approximately under the age of 7, as measurement requires patient cooperation. NIOX VERO should not be used in critical care, emergency care or in anesthesiology.

2 Product description

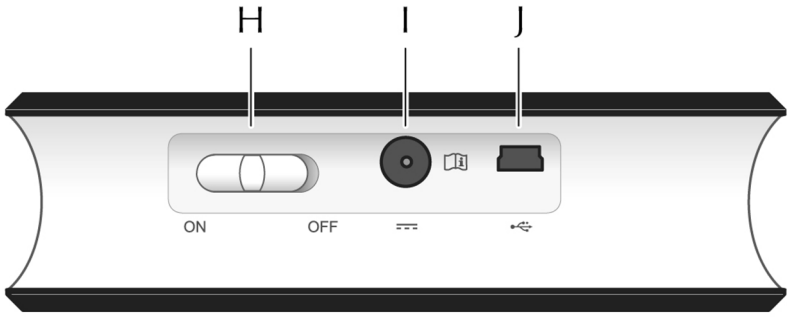
2.1 NIOX VERO® accessories and parts



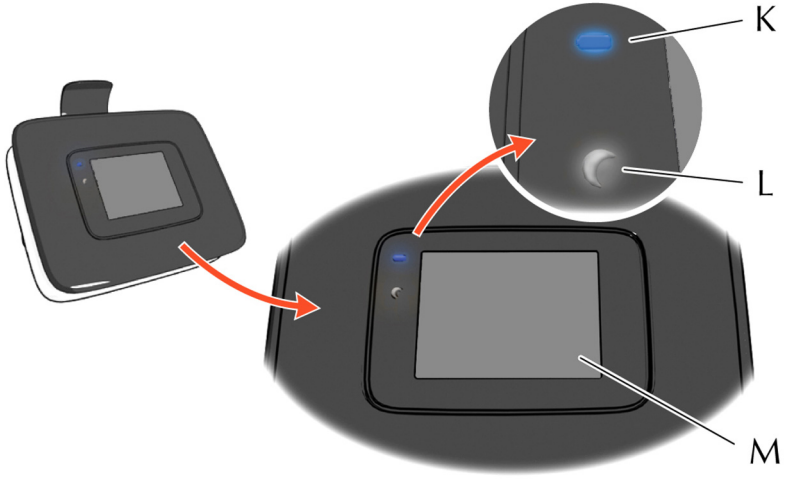
(A) Breathing handle and handle cap, (B) Sensor (supplied separately), (C) Instrument (including stand), (D) Rechargeable battery, (E) NIOX® Panel USB memory stick, (F) USB cable, (G) Power adapter and power cord, (H) Patient filter (supplied separately)

Note: *Only accessories and parts supplied by Aerocrine may be used.*

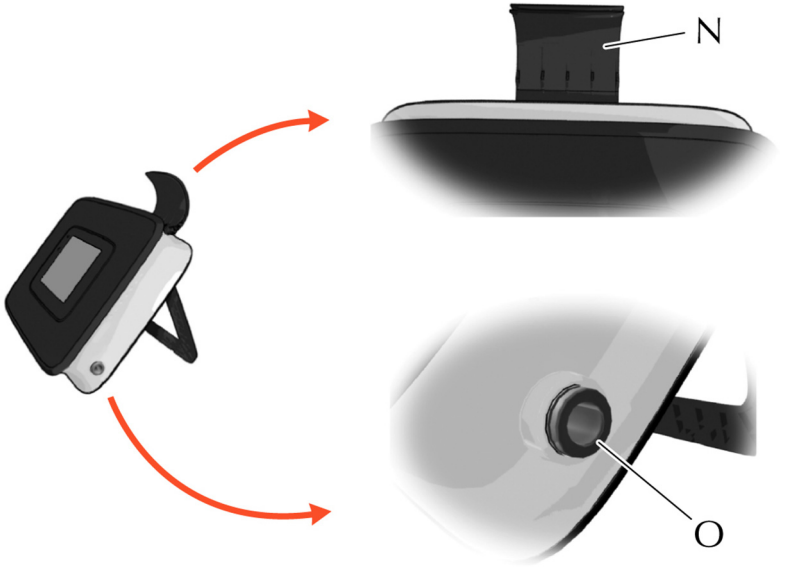
2.2 Instrument



H) ON/OFF button, (I) Power adapter port, (J) USB port



(K) Battery LED - lit when battery is charging, (L) Standby LED - blinking in Standby/Sleep mode, (M) Touch panel Display

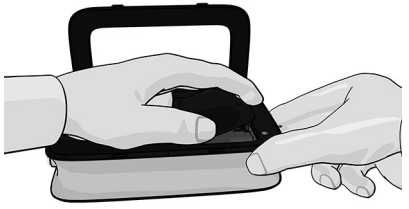


(N) Breathing handle holder, (O) Breathing handle port

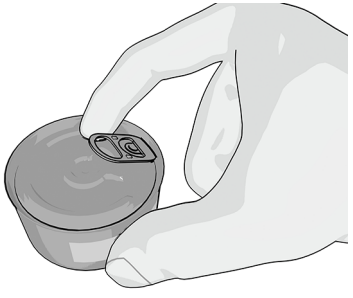
3 Installation and set up

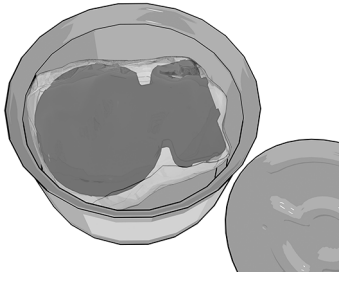
Open the package with care. Prior to installation, check that the package contains all the parts. (See page 5). A screwdriver is required for opening the compartment lid and installation of Sensor and battery. Remove the plastic film from the display.

1. Carefully place the instrument with the display facing down on a flat and clean surface, then unscrew and remove the compartment lid. There is a taper on the side of the lid for better grip when opening.



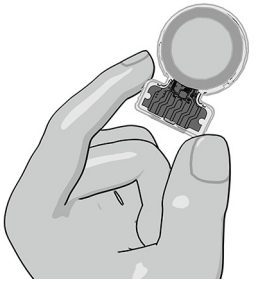
2. Open the Sensor can.





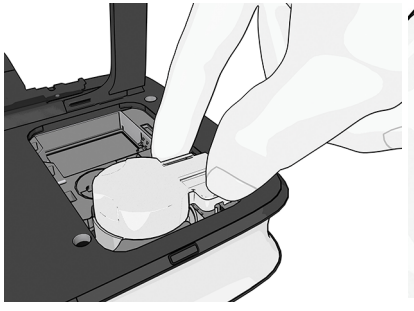
WARNING! Open the Sensor can with care. The inside of the opening may have sharp edges.

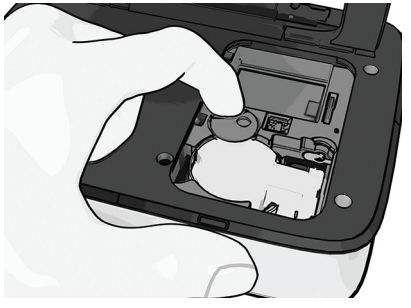
3. Open the Sensor package.



WARNING! Do not touch or clean the white Sensor membrane.
CAUTION! The Sensor should only be stored in its original unopened package or installed in a NIOX VERO® instrument.

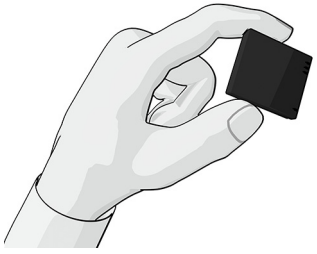
4. Insert the Sensor and turn the swivel clockwise until locked.



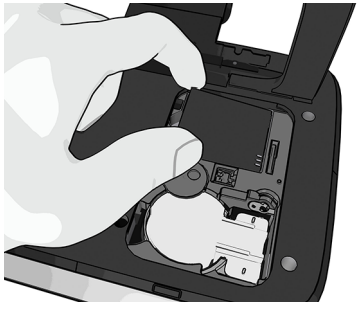


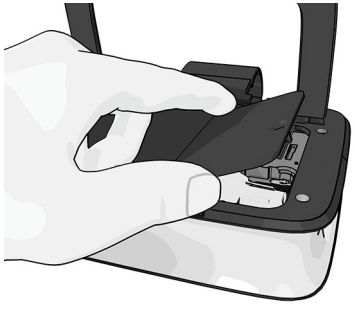
5. Open the battery package.

Note: *Only use the correct rechargeable battery supplied by Aerocrine. Type No BJ-G510039AA, Article No 12-1150*



6. Insert the rechargeable battery and replace the lid. Tighten the screw by using a screwdriver.

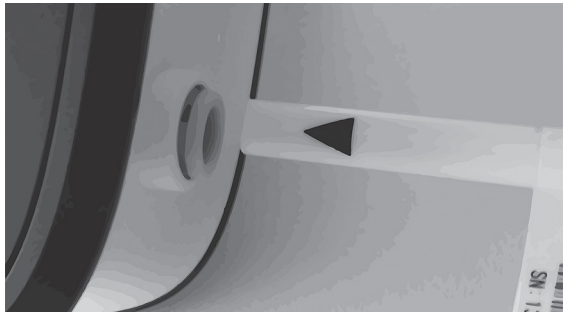




7. Take the breathing handle tube and push the end of the tube into the breathing handle port slowly until the triangle is no longer visible. The breathing handle and the patient filter are Applied parts Type B.

Note: *Only attach the breathing handle supplied by Aerocrine. Article No 12-1010*

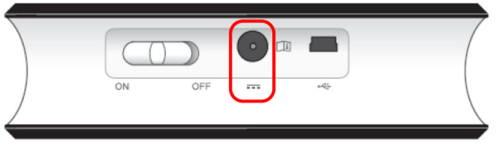
Note: *Use care not to bend the handle tube.*



Note: *The triangle should not be visible when assembled correctly.*

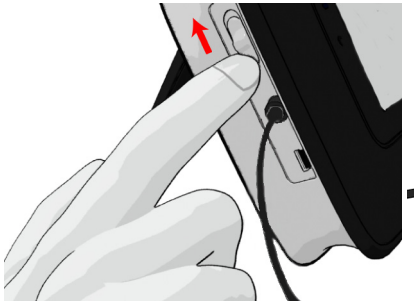
8. Attach the power adapter to the instrument and then to the power outlet. When installing the unit, either use a socket outlet with a readily accessible power switch, or connect the AC cord plug to an easily accessible socket outlet near the equipment. If a fault should occur during operation of the unit, use the power switch to cut the power supply, or remove the AC cord plug.

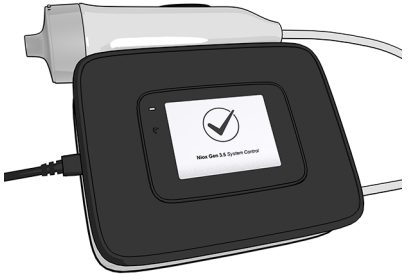
Note: *Only use the power adapter supplied by Aerocrine with the instrument. Article No 12-1120.*



9. Position the instrument with the stand folded out.

10. Start the instrument by sliding the ON/OFF button to **ON** and allow the instrument to start up and perform the internal check.



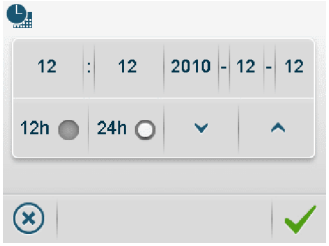


CAUTION! After inserting a new Sensor it is recommended to wait for three hours with the instrument switched on before performing a measurement.

11. When the internal check is completed, the main menu appears.

12. Select the **Settings** button on the main menu.
13. Select **Time and date**.

This opens the Time and date setting view.



14. Select between 12h US and 24h ISO time and date format.

15. Set time by pressing the button for hour. It changes color to blue. Change the value to the current hour by pressing the increase or decrease buttons. Repeat this procedure for minute, year, month and day.

16. Select **OK** to accept the changes and return to the main menu.

    The **Undo** button closes the view without saving any changes.

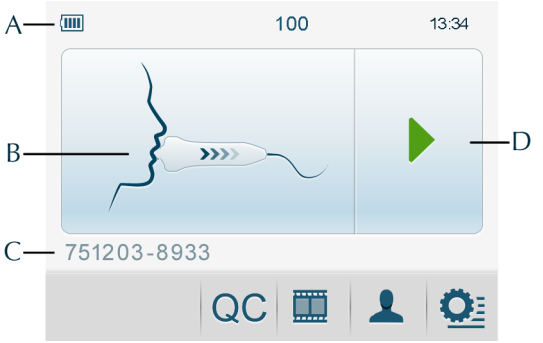
17. Select the **Settings** button on the main menu.
18. Select the **Breathing handle** button. This opens the Breathing handle view.
19. Select the **Reset Breathing handle** button. The breathing handle information view opens to confirm the insertion of the breathing handle.
20. Select the **OK** button to confirm insertion of a new breathing handle. This sets the remaining measurements to 1000 and expiry date one year from the current date.
    The **Return** button returns to Settings view without registering change.

4 User interface

4.1 Main and settings view

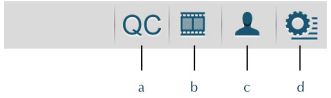
This section describes the main view, settings view, menus and symbols. Buttons and symbols are further described on page 42.

4.2 Main View



(A) Status bar, (B) Instructive demonstration, (C) Patient ID, (D) Start measurement button

4.2.1 Main menu

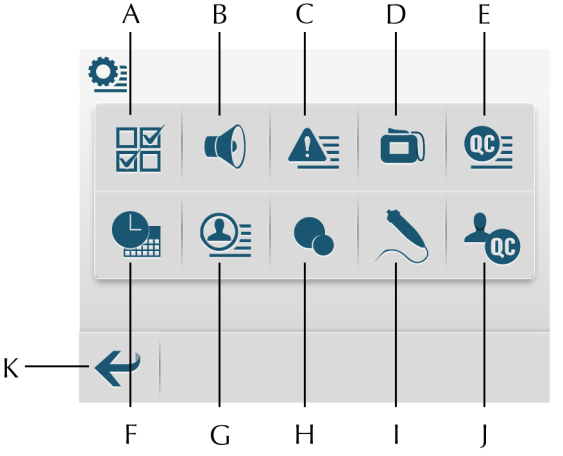


(a) QC Users (b) Demo, (c) Patient ID entry, (d) Settings

4.2.2 Status bar

(e) Battery status, (f) USB connection (in this position a Bluetooth connection may be indicated instead), (g) QC warning, (h) Breathing handle has expired or is about to expire - blinking symbol, (i) Instrument has expired or is about to expire - blinking symbol, (j) Sound disabled, (k) Sensor status and number of remaining measurements, (l) Temperature outside of specification, (m) Humidity outside of specification, (n) Time

4.3 Settings view

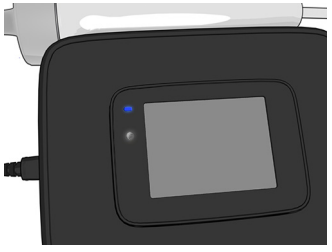


(A) Modes configuration - see page 16, (B) Volume settings - see page 16, (C) Alert log see page 17, (D) Instrument & Sensor info - see page 18, (E) QC log - see page 22, (F) Time and date settings - see page 16, (G) Measurement log - see page 17, (H) Ambient measurement - see page 16, (I) Breathing handle status and settings - see page 35, (J) QC tester info - see page 22, (K) Return to main view

5 Using NIOX VERO®

5.1 Start the instrument from power save mode

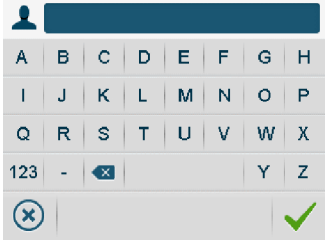
If NIOX VERO® is in **standby** or **sleep mode** simply touch the display to activate it.



5.2 Register patient ID (optional)

Note: *If Patient ID is used, it must be entered before each measurement, even if it is the same patient. Local Regulations on Patient information privacy must be considered when using unique patient identifiers.*

1. Select the **Register patient ID** button from the main menu.



2. Enter up to 12 characters (alpha or numeric).
3. Select the ABC-button to activate a keyboard with the alphabet. The 123-button changes view back to the numerical keyboard.
4. Select **OK** button to confirm the registration.

   Use the **Erase** button to erase.
   Use the **Undo** button to undo a registration.

5.3 Measure FeNO

Verify proper preparations before performing a measurement with NIOX VERO®. A basic preventive inspection is recommended before each use (see page 35).

WARNING! The patient filter is for single use only.

5.3.1 Preparation for measurement

1. Lift the breathing handle from the holder and remove the handle cap.
2. Obtain a new patient filter. Attach the patient filter to the breathing handle. Make sure to twist the patient filter in place until it clicks.

Note: *Do NOT use sharp objects to open the packaging for the patient filter. Do not touch the filter membrane.*

Note: *Patient filters should be used immediately after opening.*

Note: *There is a risk of leakage if the filter is not correctly attached to the breathing handle and this may result in incorrect measurement values.*

Note: *Do not switch OFF the instrument during measurement procedure.*

3. Give the breathing handle to the patient and guide the patient to provide a breath sample as described in the next section.

5.3.2 Measurement

1. Empty the lungs by breathing out thoroughly.
2. Close the lips around the mouthpiece on the patient filter so that no air leakage occurs.

3. Inhale deeply through the patient filter to total lung capacity. During inhalation, the cloud on the display moves upwards.

Note: *The procedure is activated by inhaling air from the handle or by pressing the start measurement button.*

4. Exhale slowly through the filter while keeping the cloud within the limits as indicated on the display (the white lines).

5. The instrument display and audio signals guide the user to the correct exhalation pressure.

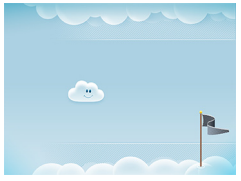
A continuous sound indicates correct pressure with a frequency proportional to the pressure.

An intermittent high frequency sound - too strong pressure

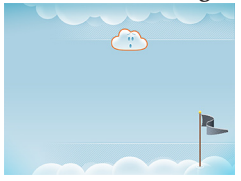
An intermittent low frequency sound - too weak pressure

Exhalation with:

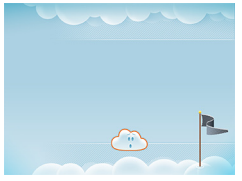
Pressure correct



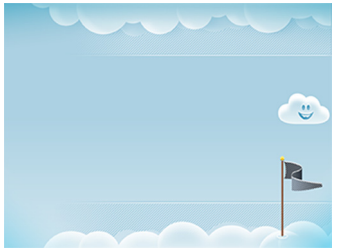
Pressure too strong



Pressure too weak

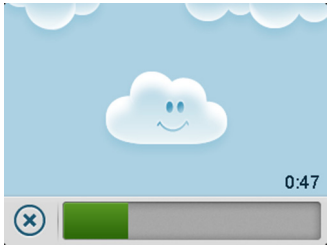


6. Exhale until the cloud has passed the flag.

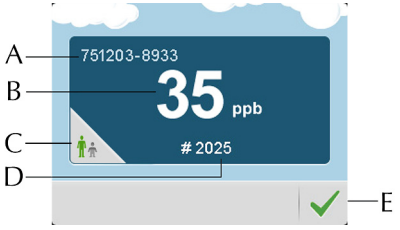


7. The instrument will analyze the sample and generate a result in approximately one minute.

Note: *Do not exhale or inhale through the patient filter during the analysis process.*



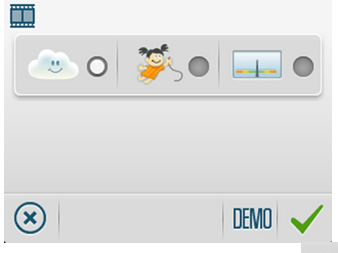
8. The result is then displayed: (A) Patient ID - if applicable, (B) FeNO value in ppb (parts per billion), (C) Measurement mode, (D) Measurement sequence number, (E) OK - returns to main view.



5.4 Demonstration mode

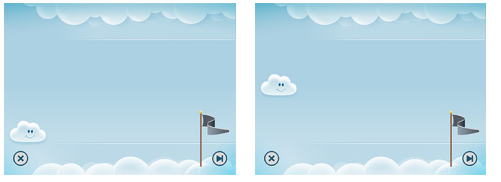
To help professionals in guiding patients, the instrument contains three animated demonstrations with visual and audio guides of the different stages of a measurement procedure.

1. Select the **Animation** button on the main menu.
2. Select which animation to use Cloud, Balloon or Meter

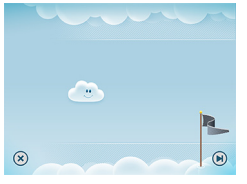


3. Select the **Demo** button. DEMO
4. Select the **forward** button to move to the following sequence.
5. The **undo** button closes the demonstration and returns the animation select.
6. Select **OK** button to confirm the changes.
7. The **undo** button returns to the main menu without saving changes.

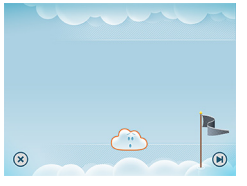
a. Inhalation through the breathing handle.



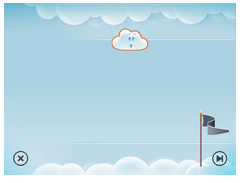
b. Exhalation through the breathing handle with correct pressure.



c. Exhalation through the breathing handle with pressure too weak.



d. Exhalation through the breathing handle with pressure too strong.



5.5 Measure ambient NO

Note: *An ambient measurement may be requested by customer support during troubleshooting.*

Note: *An ambient measurement is counted as one measurement on NIOX VERO® Sensor and the instrument.*

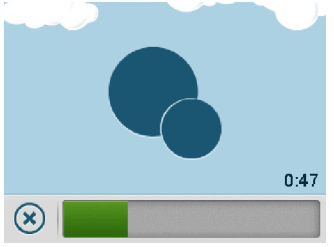
1. Attach a patient filter to the breathing handle until it clicks into place.

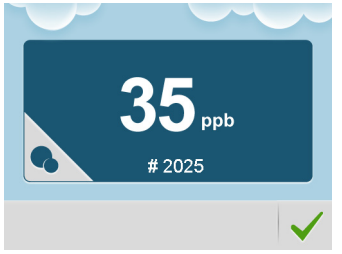
2. Select the **Settings** button on the main menu.

3. Select **Ambient Measurement** button.

4. Select the **Start measurement** button.

5. The progress bar is visible until the measurement is finished and the result is displayed: Ambient measurement value (in ppb), measurement mode, and measurement sequence number.





5.6 Change settings

5.6.1 Change time and date

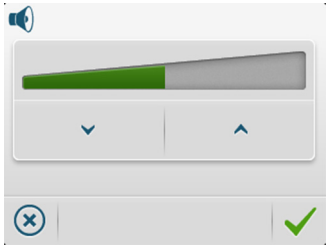
1. Select the **Settings** button on the main menu.
2. Select the **Time and Date** button.

For more details refer to page 9.

5.6.2 Change sound volume

1. Select the **Settings** button on the main menu.
2. Select the **Sound** button.

3. The settings for sound and volume opens.



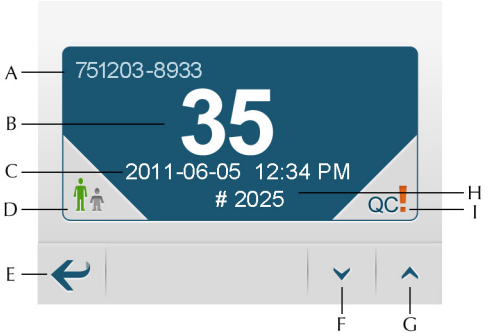
4. Select **increase/decrease** to adjust volume.
5. The volume bar indicates the set volume.
6. Select the **OK** button to save settings and return to the Settings view.

   The **Undo** button closes the view without saving changes.
7. The status bar indicates mute status when the sound volume is set to zero.

5.6.3 View measurement logs

All measurement results are stored in the instrument and can be viewed at any time.

1. Select the **Settings** button on the main menu.
2. Select the **Patient measurements log** view button.
3. The selected log will display the following:



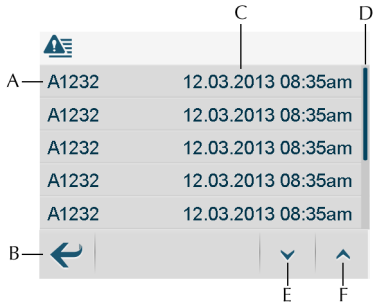
(A) Patient ID - if defined, (B) FeNO value, (C) Measurement date and time, (D) Measurement mode, (E) Return to settings, (F) Backward, (G) Forward, (H) Measurement sequence number, (I) QC Warning, only shown if the daily QC measurement is not performed or if the results from the QC are outside limits

4. Browse through the measurement logs using the **backward** and **forward** buttons.
5. Select the **Return** button to return to settings.

5.6.4 View alert logs

Alerts are stored in the instrument and can be viewed at any time. The alert codes are for Aerocrine Customer Support use.

1. Select the **Settings** button on the main menu.
2. Select **Alert log** button.



(A) Alert code (for customer support purpose only), (B) Return - returns to previous view, (C) Date and time of alert, (D) Scroll list (blue), (E) Backward (F) Forward

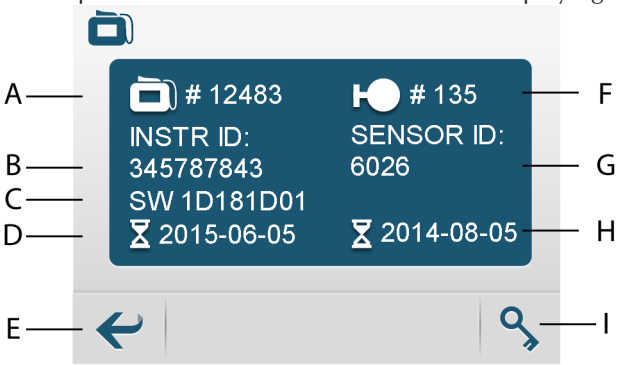
3. Select the **Return** button to return to settings.

5.6.5 View instrument information

Detailed information about the instrument and Sensor can be viewed.

1. Select the **Settings** button on the main menu.
2. Select the **Instrument** button.

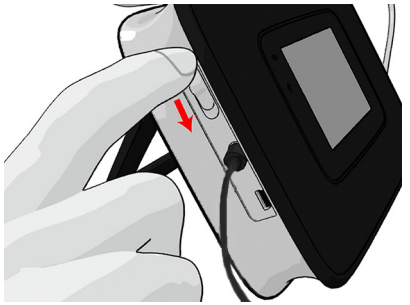
3. This opens the Instrument information view displaying the following:



(A) Numbers of remaining measurements on the instrument, (B) Instrument serial number, (C) Software version number (D) Instrument expiration date, (E) Return to settings, (F) Numbers of remaining measurements on the Sensor, (G) Sensor serial number, (H) Sensor expiration date, (I) Enter configuration code (only used on request from Aerocrine)

5.7 Turn off the instrument

1. To turn off the instrument, slide the **ON/OFF** button to **OFF**.



Note: *Before transportation remove the used patient filter (if still attached) and attach the handle cap.*

Note: *Always use a closed bag or case (NIOX VERO® bag recommended) for transportation and storage of the instrument.*

5.8 External Quality Control (QC) procedure

The external Quality Control is one of the procedures that ensures the system is operating within the specifications.

Note: *The Quality Control function must always be activated as a daily QC measurement is mandatory when the instrument is clinically used.*

A QC icon in the status bar on the screen indicates that a daily external QC assessment is needed or that there are not any currently qualified QC individuals who have completed their initial 4 qualification attempts.

The external Quality Control consists of two parts. One positive control from a qualified staff member with a stable FeNO value providing a normal biological FeNO sample and a negative control consisting of a NO free gas sample automatically generated from ambient air.

NIOX VERO® will allow for one daily QC measurement that will not affect the number of remaining tests on the NIOX VERO® Sensor. (During the first 20 days of instrument start-up, a maximum of seven QC testers can be qualified without impact to the number of remaining tests on the Sensor.)

Note: *It is also possible to store the QC users in a database, see chapter "6.7.6 Perform QC measurement" for information.*

5.8.1 Selection and qualification of QC testers

A minimum of one individual (two individuals are recommended) needs to qualify for this procedure. If possible, identify one or two individuals as a back-up.

Identify the staff members who will perform the Quality Control and meet the following criteria:

- Over 18 years of age.
- No ongoing cold or known airway disease.
- Non-smoker.
- Expected stable FeNO values between 5 and 40 ppb.
- Preferably no allergies (except seasonal, see below) or asthma.

A QC tester will be qualified over the course of four days within a seven day period

Note: *After a QC tester has been qualified, if the most recent QC measurement is older than 30 days, then the qualification is suspended and the QC tester needs to re-qualify according to the qualification procedure. Perform four QC measurements, one per day within seven days, according to the QC measurement section, in order to qualify a QC tester.*

A mean value is calculated from the three qualifying measurements that must be between 5-40 ppb for the QC tester to be qualified. The QC measurement on the fourth day (daily QC) must be within ± 10 ppb from the mean value and the negative control approved. If this has been met the Quality Control has passed for that staff member and the instrument is ready for clinical use. The moving mean value is recalculated when the QC tester performs a QC measurement after seven days.

5.8.2 QC measurement

This procedure applies for qualification and daily QC measurements. The instrument will prompt for a daily QC procedure by showing QC in the status bar or when there are no staff who are currently qualified as a tester. Always consider the following in order to obtain reliable results.

Before any measurement:

- Avoid nitrate rich food for up to 3 hrs before the measurement.
- Avoid strenuous exercise at least 1 hour before the measurement.
- Preferably do not perform a measurement in case of:
  - Ongoing cold
  - Acute seasonal allergy
- Always attach a new patient filter for each new QC tester.

1. Select **QC**.

2. Select **QC Settings** to verify which QC IDs are available.

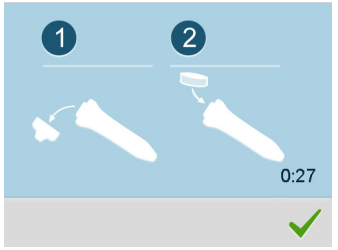
Note: *Each QC tester must select an individual number.*

3. Select an available **QC ID**.
4. Empty the lungs by breathing out thoroughly.
5. Put the NIOX VERO® patient filter to your mouth making sure no air leakage occurs.
6. Inhale deeply through the patient filter to total lung capacity. During inhalation, the cloud on the display moves upwards.

7. Exhale slowly through the filter while keeping the cloud within the limits as indicated on the display (the white lines).

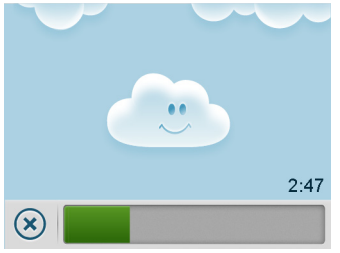
8. Exhale until the cloud has passed the flag.

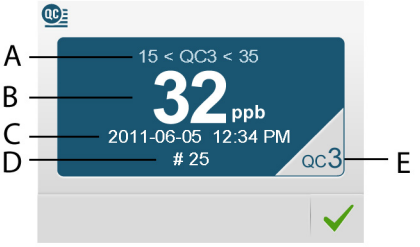
9. Remove the patient filter and immediately attach the handle cap.



10. Press ✓ to proceed.

11. The progress bar is visible until the analysis phase is complete. The QC control result is displayed.

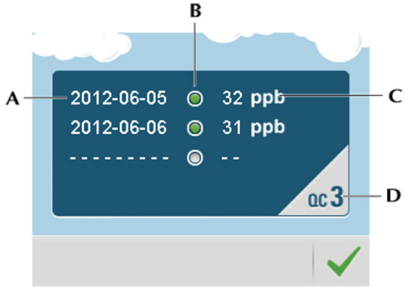




(A) Control result FeNO value limits (mean value +/- 10 ppb), (B) Control result in ppb, (C) QC Measurement date and time, (D) Measurement sequence number, (E) QC tester number

12. Remove the handle cap.
13. Press ✓ to return to main menu.

Note: *During the qualification days of a new QC tester the result is displayed as presented below.*



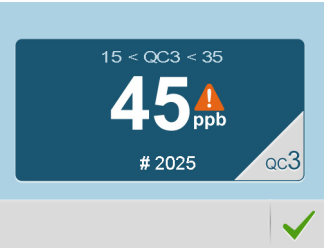
(A) Date of measurement, (B) Status button (green = within specifications, white = not within specifications), (C) Mean value in ppb, (D) QC tester number

Press ✓ to return to main menu.

Repeat the QC test if the positive and/or the negative control fail. If the QC failure persists, discontinue use of NIOX VERO® and contact Aerocrine Customer Support.

Note: *The prompt to QC the device will remain if the QC measurement was performed by a non-qualified QC candidate. It is not an indication of an unsuccessful (failed) QC measurement.*

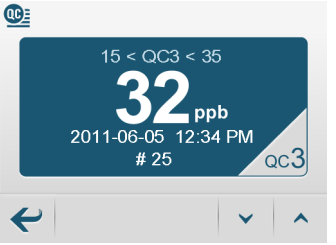
Note: *If the daily Quality Control is not successfully performed, or if the results from the QC are outside limits, a warning alert will be displayed beside the measurement value.*



5.8.3 View QC logs

1. Select the **Settings** button on the main menu.
2. Select the **QC log** button.

   The QC log window opens.

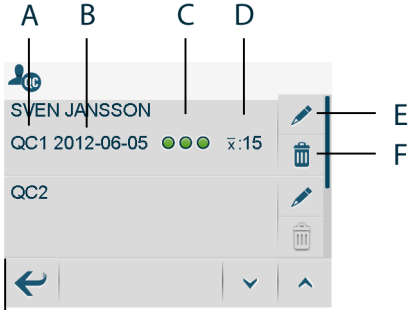


3. Browse through the measurement logs using the backward and forward buttons.

5.8.4 View QC information

After day 3 the QC qualification procedure is complete. A qualified tester is displayed in the QC tester view

1. Select the **Settings** button on the main menu.
2. Select **QC tester** button.
3. The QC qualifying results are displayed as follows.



(A) QC tester number, (B) Last date to perform a QC measurement without having to re-qualify the QC tester, (C) Status buttons (green = within specifications, white = not within specifications), (D) Mean value in ppb, (E) Edit button, (F) Delete button

Note: *To add or edit a name to a QC tester number press the Edit button.*

4. Select the Return button to return to settings.

5.8.5 Reset QC tester

This instruction will delete the data for the selected individual.

1. Select the **Settings** button on the main menu.
2. Select **QC Settings** to verify which QC IDs are available. The following window is displayed:

3. Select the **Delete** button for the user ID to be reset.
4. Select to accept deletion of the selected user ID.

6 Using NIOX VERO® with NIOX® Panel

Your NIOX VERO® instrument can be used together with NIOX® Panel. NIOX Panel is a PC application and visual aid allowing you to operate the instrument from your PC.

6.1 Warnings

- NIOX® Panel shall only be operated by trained healthcare professionals.
- Operate NIOX® Panel as stated in this manual. Aerocrine accepts no responsibility for damaged equipment or faulty results, if the equipment is not handled according to this manual.
- When selecting an accessory for your NIOX® Panel product keep in mind that an accessory not recommended by Aerocrine AB may result in loss of performance, damage to your NIOX® Panel product, fire, electric shock, injury or damage to other property. The product warranty does not cover product failure or damage resulting from use with non approved accessories. Aerocrine takes no responsibility for health and safety problems or other problems caused by the use of accessories not approved by Aerocrine.
- If the equipment is used in a manner not specified by Aerocrine, the protection provided by the equipment may be impaired.
- Modification of NIOX® Panel application is not allowed.
- Do not use damaged components.

6.2 Installation of NIOX® Panel

NIOX® Panel System requirements

- Windows® XP*(32 bit), Windows® Vista(32 bit), Windows®7 or Windows® 8/8.1 Pro (RT versions excluded)
- .NET Framework 4.0
- 1 GHz or faster processor
- 256 MB RAM (512 MB RAM recommended)
- 250 MB of video graphics RAM
- 250 MB of available hard-disc space
- 1024x768 screen resolution
- Generic Microsoft Bluetooth driver**

* Service Pack 3
** Needed for Bluetooth communication

Note: *If the computer does not fulfill the system requirements, see note on page 28.*

The NIOX® Panel software is supplied on a USB storage device.

1. Insert the USB storage device in the computer's USB port.
2. Select the file named **setup.exe**.
3. If .NET Framework, VC++ 2010, XNA or SQL Server Compact is not installed, an installation wizard for each of the programs opens, one at the time.
4. Select to accept license agreement for the program.
5. Follow the instructions and wait for the programs to install.
6. The Installation wizard for NIOX® Panel opens.

7. Follow the instructions and install the program.

Note: *Last step of the installation "Removing backup files" takes a few minutes.*

8. When the installation is complete, click **Close**.
9. The application is now available on the start menu.

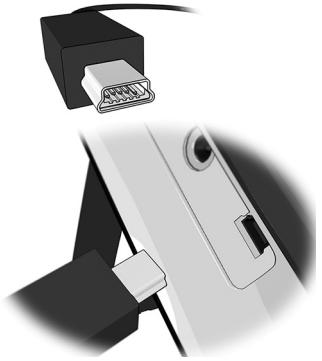
6.3 Connect to a PC via USB

In order for NIOX VERO® to be able to communicate with a PC, you may use a USB cable.

An alternative option is Bluetooth communication (see how to enable Bluetooth in the next section).

Note: *Only USB cables supplied by Aerocrine may be used. Article no 12-1002*

1. Plug the USB cable into the instrument and connect it to a PC.



2. An enabled USB connection is displayed on NIOX VERO with a symbol on the status bar.

Note: *If the instrument is in sleep or power saving mode no connection will be established.*

6.4 Connect to a PC via Bluetooth

6.4.1 Activate Bluetooth functionality

1. Select the **Settings** button on the main menu.
2. Select the **Measurement Mode** button.
   This opens the Configuration modes view.
3. To enable Bluetooth, check the checkbox.

   (Unchecking the box disables Bluetooth communication.)

Select **OK** to confirm change.
This returns to the Settings view.
An enabled Bluetooth function is indicated by a symbol on the status bar (provided that the instrument is not connected to a PC via cable).

Refer to the PC User Manual on how to enable Bluetooth on the PC.

6.4.2 Connect by Bluetooth in NIOX® Panel

1. Select in the NIOX Panel window
2. A search view opens, select to search for devices.
3. Select the instrument and click OK.

Note: *If the instrument is in power saving mode no connection will be established.*

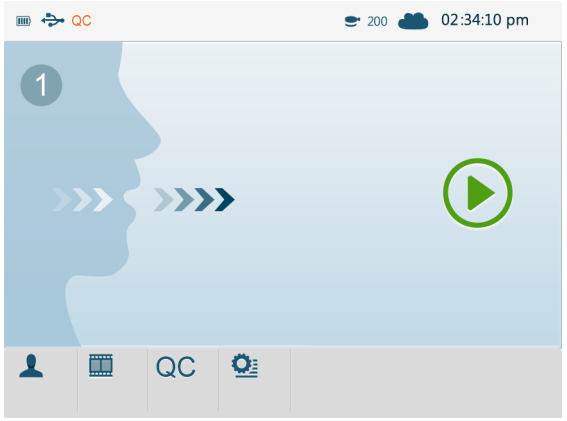
6.5 Setup

1. Turn on the PC and monitor.

2. Turn on the instrument.
3. Select the **Start** or the **Windows** button normally found in the left lower hand corner of your monitor.
4. Select **NIOX® Panel** from the program list.
5. Plug the USB cable into the USB port on the NIOX VERO® and connect it to the USB port on the PC or connect by Bluetooth. This icon is shown on the display to indicate that a connection is established and NIOX VERO is running remote controlled.

6. The NIOX Panel application opens and you can start to operate your NIOX VERO instrument via your PC

Note: *When starting NIOX Panel for the first time the connectivity details dialog opens.*



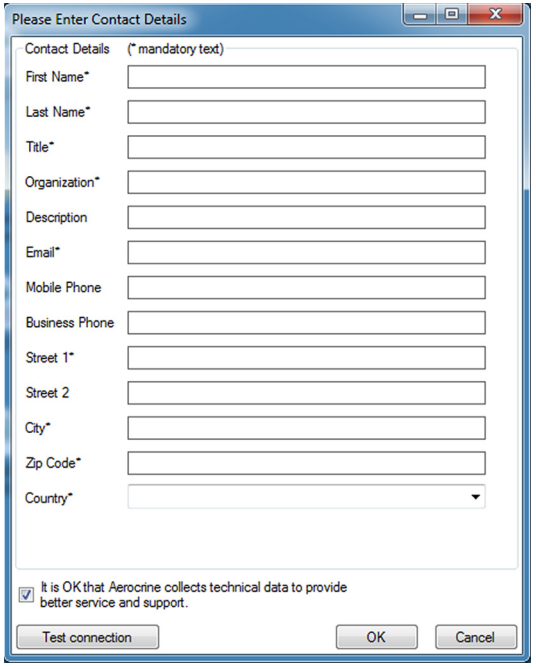
6.5.1 NIOX Panel connectivity module

The connectivity module in NIOX Panel utilizes Microsoft's secure cloud service, Microsoft Azure, to automatically transmit technical data from the device via the internet to Aerocrine.

Technical data such as time stamp, alert codes and number of remaining measurements on the device and sensor are received. This information will ensure better service and support.

Aerocrine recommends completion of the details dialog box to allow receipt of technical data and provide better service and support functions to its customers.

Mandatory fields are marked with a *. Complete these, leave the box checked, and click OK to continue.



When connection to Microsoft Azure is established a cloud icon is shown in the status bar.

If the connection to Microsoft Azure is lost or the user has chosen to not send technical data, the cloud icon is crossed over .

To decide at a later stage to allow Aerocrine to collect data, press cancel and the dialog box will open again next time NIOX Panel is started, or click on the cloud icon in the status bar.

To reject collecting of Aerocrine technical data (not recommended) uncheck the box in the bottom of the window and click OK.

Note: *Only technical data and no patient data is collected by Aerocrine.*

Changing contact details

To edit contact details click on the cloud icon in the status bar to open the contact details dialog box.

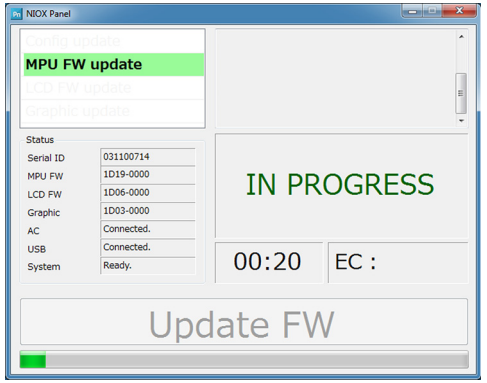
6.6 Firmware update

Note: *If NIOX VERO firmware is older than 1D1B-xxxx the firmware needs to be updated.*

Note: *Do not disconnect the USB or power cable during firmware update.*

1. Connect the instrument via USB. Make sure that the power cable is connected.

2. Press the update firmware button and wait for the update to be finished.



3. The instrument will automatically restart and reconnect to NIOX Panel when the update is finished.

6.7 Using NIOX® Panel

Note: *The buttons, symbols and views are similar on NIOX Panel and on NIOX VERO.*

6.7.1 Measure FeNO

See “Measure FeNO” on page -12.

CAUTION! Do not disconnect the instrument from the PC during measurement and analyzing process.

Note: *If the computer does not fulfill the system requirements it may still be possible to run NIOX Panel.*
To start a measurement select the Win XP animation.
It is recommended to press the “start measurement” button to initiate the measurement.

6.7.2 Demonstration mode

See “Demonstration mode” on page -15.

6.7.3 Change settings

See “Change settings” on page -16.

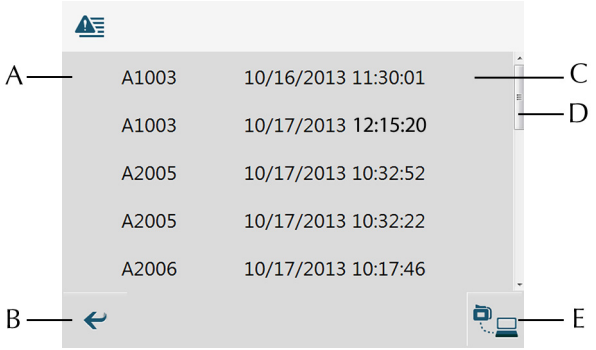
6.7.4 View measurement logs

See “View measurement logs” on page -17.

6.7.5 View alert logs

Alerts are stored in the instrument and can be viewed at any time. The alert codes are for Aerocrine Customer Support use.

1. Select the **Settings** button on the main menu.
2. Select **Alert log** button.



(A) Alert code (for customer support purpose only), (B) Return - returns to previous view, (C) Date and time of alert, (D) Scroll list (blue),
(E) Download service data (only used upon request by Aerocrine)

6.7.6 Perform QC measurement

There are two options to perform a QC measurement when NIOX Panel is used:

- Either stand alone like in chapter "5.8.2 QC measurement"

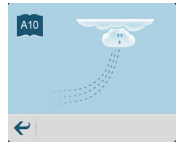
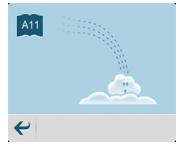
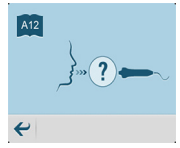
or

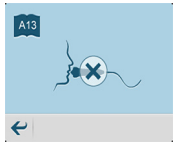
- If NIOX Panel is connected to the NIOX database it is possible to create the QC users and store the QC measurements in the database. *This allows a QC user (after qualification) to qualify a new instrument with just one QC measurement.* For instructions how to create QC users in the database see NIOX Patient User Manual.

7 Troubleshooting

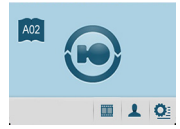
7.1 Alert codes and actions

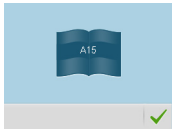
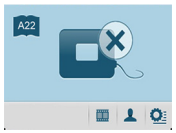
Alert messages and other information are shown as a code on the instrument display. The tables below provide the alert codes and recommended actions to be taken for an alert code. If the alert persists, contact your local Aerocrine representative or Aerocrine Customer Support.

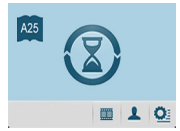
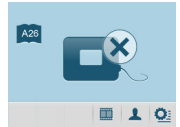
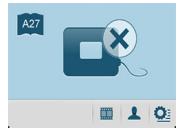
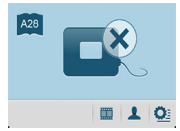
User alerts	Screen	Action
A10		**Exhalation too strong** Press Return and repeat the measurement with less exhalation force.
A11		**Exhalation too weak** Press Return and repeat the measurement with greater exhalation force.
A12		**Measurement failed** No exhalation detected or the user failed to exhale within 15 seconds from inhaling. Press Return button, restart the measurement and exhale into the instrument directly after inhalation.

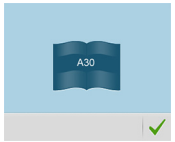
User alerts	Screen	Action
A13		**Analysis interrupted** Repeat the measurement and do not breathe through the handle during analysis.
A21		**Measurement failed** Remove any sources of disturbance (such as cordless phones/mobile phones or gas emitting appliances). Then press Return. When the instrument is ready for use repeat the measurement. If the alert persists, unplug and reconnect the power supply unit to restart the instrument.

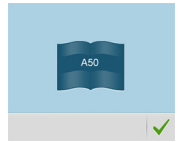
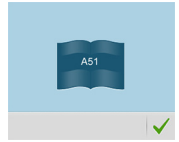
Instrument alerts	Screen	Action
A01		**Unstable temperature** Make sure that the ambient temperature is between 50°F and 95°F. Wait for the Sensor to stabilize. If necessary move the instrument to another location and restart the instrument.

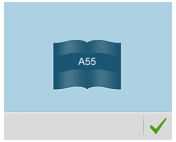
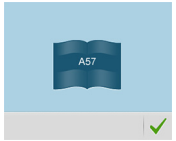
Instrument alerts	Screen	Action
A02		**Sensor stabilization** Remove any sources of disturbances (such as cordless phones, mobile phones or gas emitting appliances). Wait for the Sensor to stabilize.
A03		**Unstable system** Remove any sources of disturbances (such as cordless phones, mobile phones or gas emitting appliances). Wait for the system to stabilize.
A04		**Count down time** The remaining time until the instrument is ready to use is displayed.
A05		**Lock MMI** When the instrument is connected to a PC the main view buttons will be locked.
A06		**Configuration code error** Only provided by Aerocrine upon request. The configuration code entered is incorrect. Enter correct configuration code. If this error continues to be shown contact Aerocrine Customer support.

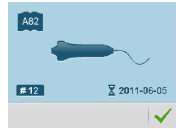
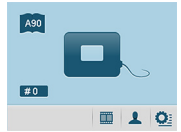
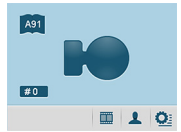
Instrument alerts	Screen	Action
A07		**Lid open warning** Check if the battery or sensor lid is open and close if needed. Click the OK button when finished.
A08		**Battery problem** Low power in battery or other failure. Change the battery and click the OK button when finished.
A09		**Condensation countdown** Too frequent use of the instrument. Remaining time until instrument has dried out.
A15		**Condensation alert** Reduce frequency of measurements. Continue measuring at this frequency causes condensation in the instrument and will make the instrument unusable for 30 minutes
A22		**Memory access failure** Contact Aerocrine Customer support.

Instrument alerts	Screen	Action
A25		**Temperature or base line failed to stabilize within 30 minutes** Check that the ambient temperature and relative humidity is within specification. If necessary, move the instrument to another location and restart the instrument.
A26		**Self test failure** The self test of the instrument failed. Restart the instrument. If alert code persists contact Aerocrine Customer support.
A27		**Internal hardware error unrecoverable** Contact Aerocrine Customer support.
A28		**Internal hardware error recoverable** Check that the Sensor, battery and lid is in its correct position, also make sure that the tube is not folded When finished restart the instrument.
A29		**Analysis failure** Ambient measurement failure. Click the OK button and obtain a new measurement.

Instrument alerts	Screen	Action
A30		**Bluetooth connection error** Check the Bluetooth connection with the PC. When finished click the OK button.
A31		**USB connection error** Check the USB connection with the PC. When finished click the OK button.
A40		**No Sensor inserted** Insert Sensor. See page 36 (replacement of sensor) or page 7(initial placement of sensor).
A41		**Sensor error** Remove any sources of disturbance (such as cordless/mobile telephones or gas emitting appliances). When the instrument is ready for measurement try to repeat the measurement. If alert persists, power off the instrument, remove and insert the Sensor and restart the instrument.

Instrument alerts	Screen	Action
A50		**Measurement failure** The measurement value does not fall between 5-50 ppb. Restart the QC tester qualification from day one.
A51		**Too many QC attempts** In one day the same test person has attempted to perform several QC measurements. Wait one day and perform the next QC measurement.
A52		**QC measurement failure** Moving mean value out of range. Restart the QC tester qualification from qualification day one.
A53		**NO-scrubber result out of range** NO scrubber result over 10 ppb. Check that the handle cap was attached when instructed. Restart the QC measurement. If continuously shown replace the NO scrubber.

Instrument alerts	Screen	Action
A54		**QC daily result too low** QC daily result lower than limits from moving mean.
A55		**QC daily result too high** QC daily result higher than limits from moving mean.
A56		**Handle cap time out** Failure to press the forward button in time (within 2.5 min.). Repeat the QC measurement and make sure to press the forward button immediately after the Handle Cap is attached.
A57		**NO scrubber analysis error** NO scrubber analysis phase error. Restart the QC measurement.

Instrument alerts	Screen	Action
A80		**The instrument is about to expire** Order a new instrument. This alert is visible when less than 500 measurements remain or less than 120 days until expiry date. Press OK to acknowledge.
A81		**The Sensor is about to expire** Order a new Sensor. This alert is visible when less than 10% of the measurements remain or less than 2 weeks until expiry date. Press OK to acknowledge.
A82		**The breathing handle is about to expire** This alert is visible when less than 100 measurements remain or less than 2 weeks until expiry date. Press OK to acknowledge. Prepare to change breathing handle.
A90		**All measurements on the instrument have been used** It is still possible to view measurements stored in the instrument memory.
A91		**All measurements on the Sensor have been used.** Replace the Sensor, see page 36.

Instrument alerts	Screen	Action
A92		**Instrument expiration date has passed** It is still possible to view measurements stored in the instrument memory.
A93		**Sensor expiration date has passed.** Replace the Sensor, see page 36.
A94		**The breathing handle has expired** Press OK. Change breathing handle. See page 35. **CAUTION!** The breathing handle's NO scrubber contains potassium permanganate and should be disposed of as hazardous waste in accordance with local waste disposal regulations.
A95		**Breathing handle expiration date has passed** Replace the handle, see page 35. It is still possible to view measurements stored in the instrument memory.

8 Preventive care

8.1 General care

In the following sections, actions for preventive care and maintenance are described. Do NOT try to repair the instrument. Any attempt will make the warranty invalid and performance according to the specifications cannot be guaranteed.

1. Clean the instrument with a cloth dampened with soap solution. If needed, use a dampened cloth with 70% ethanol, isopropanol or similar disinfectant.

CAUTION! Minimize use of solvents

2. Clean the breathing handle with a cloth dampened with water, alcohol or soap solution.

Note: *The breathing handle and patient filter are not intended for sterilization.*

WARNING!

- The breathing handle and the instrument can not be cleaned with an aerosol
- Be careful when using disinfectants, as excess of alcohol (ethanol) might permanently damage the Sensor. Do not use spray detergents.
- Exchange the patient filter for each new patient.
- Never attempt to open the instrument (other than the Sensor and battery compartment) or to perform service to the instrument or the Sensor.
- Do not modify the handle tube.

8.1.1 Preventive inspections

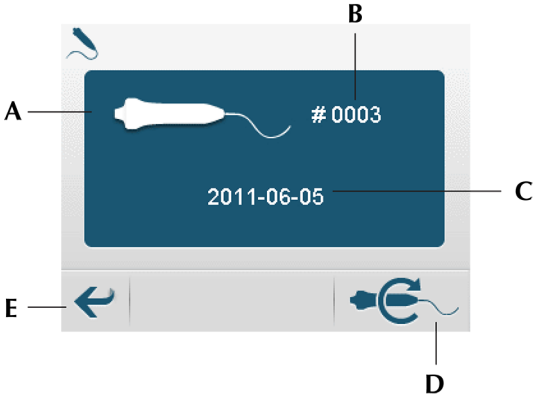
Before each measurement verify that the NIOX VERO® working properly, is not damaged and that normal operating conditions are fulfilled (see page 41).

If any item is missing or damaged, contact your local Aerocrine representative or Aerocrine Inc.

8.2 Change disposables

8.2.1 Change breathing handle

The breathing handle contains an NO scrubber which can be used for 1000 measurements or one year, whichever comes first. The breathing handle view is used for viewing the status of the breathing handle and for resetting breathing handle usage parameters.

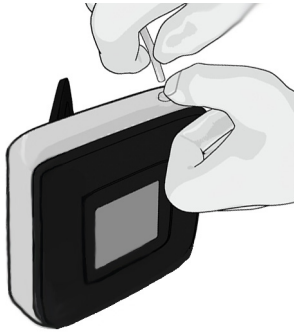


(A) Breathing handle symbol, (B) Remaining number of measurements, (C) Expiration date, (D) Breathing handle reset button, (E) Return button

Note: *The breathing handle status icon appears blinking in the status bar two weeks prior to expiration or when 10% of its capacity is left.*

Perform the following steps to change the breathing handle:

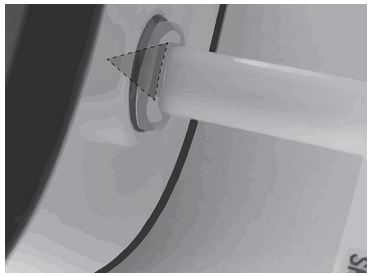
1. Place the device on its side on a level secure surface.
2. Remove the used handle from the instrument by pushing the socket into the device and gently pulling out the tube.
3. Discard the breathing handle.



CAUTION! The breathing handle contains potassium permanganate and should be disposed of as hazardous waste in accordance with local waste disposal regulations.

Do not re-use an expired breathing handle.

4. Attach a new breathing handle to the instrument by pushing the tube into the socket until the triangle is no longer visible.
5. Select the **Settings** button on the main menu.
6. Select the **Breathing handle** button.
7. Select the **Reset Breathing handle** button.

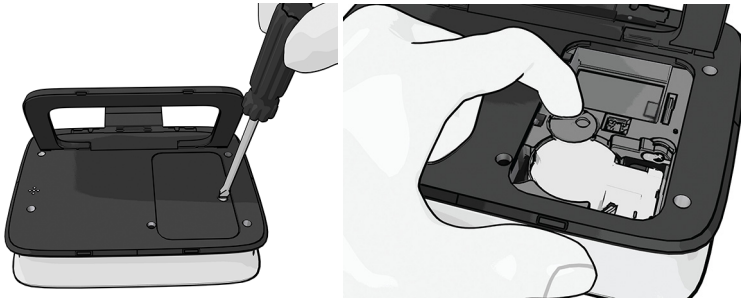


8. The breathing handle information view opens to confirm the replacement of the breathing handle. Select the **OK** button to confirm insertion of a new breathing handle and to set the remaining measurements to 1000 and expiration date one year from the current date.

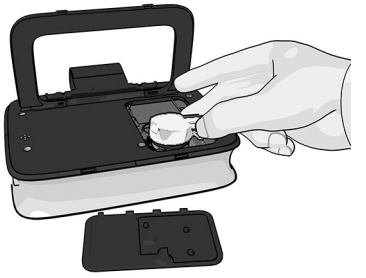
Note: *The **Return** button returns to settings view without registering change.*

8.2.2 Exchange of NIOX VERO® Sensor

1. Turn off the instrument.
2. Open the compartment on the back of the instrument using a screwdriver. Turn the swivel to release the Sensor.



3. Remove the old Sensor.
4. Replace with a new Sensor.



WARNING! Make sure to not touch or clean the white Sensor membrane.

WARNING! Be careful when opening the Sensor can. The inside of the opening may have sharp edges.

5. Turn the swivel to lock.
6. Replace the compartment lid.

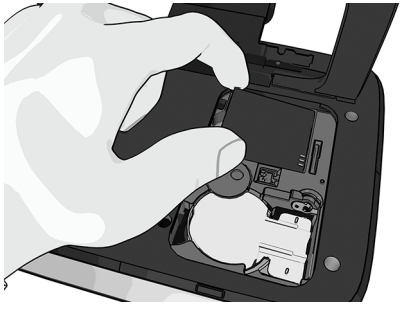
CAUTION! Make sure there are no foreign material or particles in the Sensor compartment before closing it.

8.2.3 Change battery

If the rechargeable battery is no longer charging properly, malfunctioning, or requires charging more frequent than normal, then it needs to be replaced.

Note: *Only rechargeable batteries supplied by Aerocrine may be used. Type No BJ-G510039AA, Article No 12-1150*

The battery is placed in the compartment on the back of the instrument.



1. Turn off the instrument.
2. Open the compartment lid (see previous section).
3. Remove the old battery and insert a new battery.
4. Close the compartment lid.

CAUTION! Used batteries should be recycled according to the local recycling program for rechargeable batteries.

8.3 Operational life-time

8.3.1 NIOX VERO® instrument

Minimum 5 years at time of delivery or 15, 000 measurements, whichever comes first.

The user is prompted for expiry parameters via the device display. It is not possible to perform further measurements after expiry, although stored measurement data can still be retrieved.

8.3.2 NIOX VERO® Sensor

Maximum 12 months after opening package and installation in NIOX VERO® or expiration date as stated on the Sensor, whichever comes first.

The Sensor will expire after the pre-programmed number of measurements have been depleted, or after one year (whichever comes first). When there is less than 10% of the number of the measurements left, or less than 2 weeks of use remaining, a message is shown on the display. The expiry date is also shown on the Sensor label.

8.3.3 NIOX VERO® Patient filter

The shelf life of the NIOX VERO Patient Filter in its unopened primary package is 2 years from manufacturing date.

NIOX VERO Patient Filter is for single use and must be replaced for every patient and measurement occasion.

8.3.4 NIOX VERO® Breathing handle

The breathing handle contains a NO scrubber which can be used for 1000 measurements or one year, whichever comes first.

When there is less than 10% of the number of the measurements left, or less than 2 weeks of use remaining, a message is shown on the display (blinking breathing handle symbol in the status bar).

8.4 Disposal of instrument and accessories

WARNING! NIOX VERO® and the NO scrubber in the breathing handle contain potassium permanganate. Used or expired instruments and handles should be disposed of as hazardous waste in accordance with local waste disposal regulations.

Used or expired Sensors should be recycled according to local recycling program for electronic equipment.

Used batteries should be recycled according to the local recycling program for rechargeable batteries.

Note: *There is a $LiMnO_2$ backup battery inside the instrument in addition to the replaceable and rechargeable battery.*

Note: *There is a silver-oxide battery and a $LiMnO_2$ battery in the Sensor.*

NIOX VERO® is RoHS compliant.

8.5 Return shipments

For return shipments, contact your local Aerocrine representative or Aerocrine Customer support.

9 Safety information

9.1 Warnings

See “Warnings” on page -3.

9.2 Cautions

- Mobile phones and cordless phones and gas emitting appliances might interfere with the instrument and could make it impossible to perform a measurement.
- Elevated ambient Nitrogen Dioxide (NO_2) may interfere with FeNO measurement; therefore, ensure that the patient inhales correctly according to instruction solely through the filter.
- The instrument might produce some heat during normal operation, the temperature could increase up to 9°F above the ambient temperature. Make sure that the ventilation slots are not blocked. Do not place the instrument on a bed, sofa, carpet, or other soft surface.
- Normally a maximum of 10 measurements/hour can be performed during continuous use. It is possible to perform up to 20 measurements in one hour if the instrument is paused for a minimum of 30 minutes prior to the next session of measurements. The system is not designed for continuous use, due to the risk of water condensation. Typically 30-60 measurements can be made during the course of a working day, depending on the surrounding temperature. An alert will be issued if there is a high risk of condensation due to high use frequency.
- The Sensor shall be kept in its original unopened package before installation. For transportation and storage conditions, refer to page 47.
- The Sensor is sensitive to changes in ambient temperature and

humidity. The best performance is achieved if the ambient conditions are stable. Refer to the recommended environmental conditions see page 41. Keep the unit away from windows, direct sun, radiators, stoves or open fire in order to avoid unstable conditions.

- When transporting the unit from one location to another, a prolonged stabilization period before measurement might be required. Refer to the recommended transportation conditions in the "Transport and Storage" section on page page 46. Always use a bag for transportation.
- Make sure that the gas outlet (four parallel slots to the left of the lid) on the rear side of the device is not covered.
- The device contains a Lithium-ion Battery which may induce an increased risk of heat, smoke or fire if handled incorrectly; do not open, crush, heat above 140°F or incinerate.
- Keep the Sensor out of reach of children.
- Any person who connects external equipment to signal input and signal output ports of this device has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements of IEC 60601-1.
- A PC connected to the USB connector has to be certified for one of the standards IEC 60601-1, IEC 61010-1, IEC 60950 or comparable with safety extra low voltage on the USB ports.
- The connected PC should be placed out of reach from the patient. Do not, simultaneously, touch the connected PC and the patient.

9.3 Substances disturbing FeNO measurement

Known patient factors that could interfere with FeNO measurements are described in the ATS Guidelines (Am j Respir Crit Care Med 2005; 171:912-930) as follows:

To assure correct results when performing FeNO measurement with NIOX VERO®, the following cautions apply:

- **Respiratory maneuvers** - Because spirometric maneuvers have been shown to transiently reduce exhaled NO levels, it is recommended that NO measurement be performed before spirometry. The same stipulation applies to other taxing respiratory maneuvers, unless these can be shown not to influence exhaled NO. The FeNO maneuver itself and body pletysmography do not appear to affect plateau exhaled NO levels.
- **Age/sex** - In adults there is no consistent relationship between exhaled NO level and age, but it has been reported that, in children, FeNO increases with age. In Adults, there are conflicting reports regarding the effects of sex, menstrual cycle and pregnancy, so theses patient characteristics should be recorded at the time of measurement.
- **Airway caliber** - It has been demonstrated that FeNO levels may vary with the degree of airway obstruction or after bronchodilatation, perhaps because of a mechanical effect on NO output. Depending on setting, it may be prudent to record the time of last bronchodilator administration and some measure of airway caliber, such as FEV.
- **Food and beverages** - Patients should refrain from eating and drinking before NO analysis. An increase in FeNO has been found after the ingestion of nitrate or nitrate-containing foods, such as lettuce (with a maximum effect 2 hours after ingestion) and drinking of water and ingestion of caffeine may lead to transiently altered FeNO levels. It is possible that a mouthwash may reduce the effect of nitrate-containing foods. Until more is known, it is prudent when possible to refrain from eating and drinking for 1 hour before exhaled NO measurements and to question patients about recent food intake. Alcohol ingestions reduces FeNO in patients with asthma and in healthy subjects.
- **Circadian rhythm** - Although FeNO levels are higher in nocturnal

asthma, there was no circadian rhythm in two studies, but another study did report a circadian pattern, so it is uncertain whether measurements need to be standardized for time of day. It is, however, prudent, where possible, to perform serial NO measurements in the same period of the day and to always record the time.

- **Smoking** - Chronically reduced levels of FeNO have been demonstrated in cigarette smokers in addition to acute effects immediately after cigarette smoking. Despite the depressant effect of smoking, smokers with asthma still have raised FeNO. Subjects should not smoke in the hour before measurements, and short - and long-term active and passive smoking history should be recorded.
- **Infection** - Upper and lower respiratory tract viral infections may lead to increased levels of exhaled NO in asthma. Therefore FeNO measurements should be recorded in the chart. HIV infections are associated with reduction in exhaled NO.
- **Medications and exhaled NO** - The potential effect of drugs on NO cannot be excluded, and so all current medication and time administered should be recorded. Exhaled NO falls after treatment with inhaled or oral corticosteroids in subjects with asthma and after inhaled NO synthase inhibitors. Leukotrine-axis modifiers also reduces FeNO. NO donor drugs and oral, inhaled, and intravenous L-arginine increase FeNO and nasal FeNO. Even if a certain medication does not effect NO production, it might affect the apparent level of NO through other mechanisms, such as changes in airway caliber.
- **Other factors** - The manipulation of physiologic parameters has been shown to affect FeNO. Changing pulmonary blood flow has no effect in humans, but hypoxia decreases exhaled NO, and this may occur in subjects at high altitude, particularly those prone to high-altitude pulmonary oedema. The application of positive and-expiratory pressure has been shown to increase FeNO in animals, but airway pressure in humans does not affect exhaled NO plateau levels according to most reports, although one study suggests the opposite. Many studies have examined the effect of exercise on FeNO. During exercise, according to one report, FeNO falls, whereas NO output increases, and this effect may last up to 1 hour. Others have reported that FeNO remains stable after exercise. It would seem prudent to avoid strenuous exercise for 1 hour before the measurement.
- Ethnic differences in ‘healthy’ FeNO levels have been observed. In schoolchildren Asian (boys) could have 6- 14 ppb higher FeNO levels than Caucasians boys. By contrast, Asian girls have elevated FeNO levels to a lesser extent. African-American children seem to have slightly higher ‘healthy’ FeNO levels than Caucasians; 17ppb versus 12 ppb. In African-Americans adults slightly higher average ‘healthy’ FeNO levels than Caucasians, 20 ppb versus 17-18 ppb have been observed.
- Measurement results are to be used as an adjunct to establish clinical and laboratory assessments in asthma.

9.4 Electromagnetic immunity

NIOX VERO® has been tested to comply with the emission and immunity requirements described in the parts of the IEC 61326 series for electrical equipment for measurement, control and laboratory use, and found to comply with IEC 60601-1-2:2007 General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility- Requirements and tests.

For more information see “Electromagnetic immunity” on page 49.

CAUTION! The test limits are designed to provide protection against harmful interference in a typical medical installation. However, because of the increased use of radio-frequency transmitting equipment and other sources of electrical noise emitters in the healthcare and home

environments, such as base stations for radio, cellular/cordless telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, it is possible that high levels of such interferences due to close proximity or strength of a source, may result in disruption of performance of the instrument. If abnormal performance is observed, it may be necessary to reorient or relocate the NIOX VERO®.

WARNING! NIOX VERO® should not be used adjacent to or stacked with other equipment.

9.5 Emission of electromagnetic energy

CAUTION! This equipment has been designed and tested to CISPR 11 Class B. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

For more information see “Electromagnetic emissions” on page 52.

9.6 Operating conditions

Ensure stable operating conditions by avoiding placement of the instrument in direct sunlight, near sources radiating heat, or ventilation. NIOX VERO operates during the following conditions:

- NO in ambient air up to 300 ppb

To verify NO in ambient air, perform an ambient measurement, see page 16

- Exhaled flow during FeNO measurements at 50 ml/s (3 L/min) ± 10% BTPS* during 10 seconds.
  *Body Temperature Pressure Saturated, 98.6 °F (37 °C), 14.7 psi (1013 hPa), 100% RH
- Temperature range of 50°F to 95°F
- A relative humidity range of 20% to 80%, non condensing
- An atmospheric pressure range of 700 hPa to 1060 hPa

Performance shall be sustained when measuring continuously at a rate of up to 10 measurements / hour.

Measurement cycle groups of 20 measurements / hour with sustained performance for one hour, with a minimum of 30 minutes in between each measurement cycle group of 20 measurements / hour.

9.6.1 Limited warranty

Aerocrine provides a Limited Warranty for this instrument and original accessories delivered with the instrument. Conditions are defined when the items are purchased.

Do NOT try to repair the instrument. Any attempt will make the warranty invalid and performance according to the specifications cannot be guaranteed.

9.6.2 Support

Contact your local Aerocrine representative or Aerocrine Customer Support if you encounter problems which you cannot solve with the information in this manual.

For contact details, see back cover, and provide the following information:

- Your name, address and telephone number.
- Serial number for both the instrument, handle and Sensor.
- Problem description (as thorough as possible)
- Alert codes or lists.

10 Reference information

10.1 Buttons and descriptions

10.1.1 Control buttons

OK - accept changes/verify result

Undo - closes view without saving changes

Return

Skip

Erase button

Decrease/step downwards

Increase/step upwards

Check box (not active)

Check box (active)

Radio button - off/QC not performed

Radio button - on/QC performed

Delete

Edit

Set configuration

Reset handle

Time/date (active for resetting)

Start measurement

Start ambient measurement

Demo

10.1.2 Main menu buttons

Demo

Patient ID

Settings

QC

10.1.3 Settings view buttons

Configuration

Volume

Alert logs

Instrument status

Time and date

Enable Bluetooth

Patient measurements

Ambient measurements

Breathing handle status

QC tester information

QC measurements

10.2 Symbols and descriptions

10.2.1 Status bar

Battery - fully charged

Battery ≤ 87% charge

Battery ≤ 62% charge

Battery ≤ 37% charge

Battery ≤ 12% charge

Audio - mute

Instrument connected via USB

Breathing handle - about to expire or has expired (blinking)

Instrument - about to expire or has expired (blinking)

Sensor status - followed by number of measurements remaining

Sensor status - no Sensor

Warning - temperature is not within operating conditions range

Warning - humidity is not within operating conditions range

Time

Instrument connected via Bluetooth

Connected to Microsoft Azure (Only shown in NIOX Panel status bar)

Not connected to Microsoft Azure (Only shown in NIOX Panel status bar)

10.2.2 Display

Analysis progress bar

Volume bar

General warning

Screen code - correct

Screen code - incorrect

Result screen - Ambient measurement

Cloud - pressure within limits

Cloud - goal reached

Cloud - warning pressure too high or too low

10.3 Symbol explanation

Responsible manufacturer

The product meets the requirements of applicable European directive

Electrical safety Type B applied parts:
Breathing handle and patient filter

The product should be recycled according to the local program for electronic equipment.

Consult instructions for use

Expiration date

Transport and storage temperature limitation

For single use only

IVD

In Vitro Diagnostic Device

Transport and storage humidity limitation

Transport and storage atmospheric pressure limitation

Equipment protected throughout by DOUBLE INSULATION or REINFORCED INSULATION

The Device includes a Radio Frequency (RF) transmitter (Bluetooth)

NRTL-listed

Prescription use only

11 Technical data

11.1 Dimensions and weight

Height: 145 mm
Width: 185 mm
Depth: 41 mm
Weight of instrument including Sensor: 1kg

11.2 Electrical data

Electrical safety classification:	The equipment complies with the requirements according to IEC 60601-1 Class II ME EQUIPMENT while externally powered, and as INTERNALLY POWERED ME EQUIPMENT while powered by battery.
Mains Voltage:	100-240 V ~47-63 Hz
Secondary voltage (external power adapter):	5 V ⎓
Power consumption:	< 15 VA

11.3 Noise level

< 65 dBA, at a distance of 1 m

11.4 Exhaled NO - performance data

The instrument is verified to fulfill the specified performance under the temperature range within 50 to 95 °F, relative humidity range of 20-80% and pressure range of 700-1060 hPa.

Measurement range:
FeNO: 5 to 300 ppb
Lowest Detection Limit: 5 ppb
Determination by analyzing gas concentrations around and below the detection limit. 5 ppb was the lowest detectable level.

11.5 Linearity

Squared correlation coefficient $r^2 \geq 0.998$, slope 0.95 -1.05,intercept ±3 ppb.

11.6 Precision

< 3ppb of measured value for values < 30 ppb, < 10% of measured value for values ≥ 30 ppb. Expressed as one standard deviation for replicate measurements with the same instrument, using a certified gas concentration of Nitric Oxide reference standard.

11.7 Accuracy

±5 ppb for measured values ≤ 50ppb or 10% of measured value for values > 50 ppb. Expressed as the upper 95% confidence limit, based on absolute mean of differences from certified gas concentration of Nitric Oxide.

11.8 Method comparison

< 10 ppb for values ≤ 50 ppb, < 20% for values > 50 ppb. Expressed as the difference between a NIOX MINO® FeNO value and the corresponding FeNO value measured with NIOX VERO® instrument from Aerocrine.

11.9 Inhalation parameters

Inhale to TLC (Total Lung Capacity) before start of exhalation. Inhalation in instrument is triggered by a pressure of -3 cm H_20.

11.10 Exhalation parameters

Exhalation time: Standard mode: 10 s (clinical use)
All exhalations are to be performed at an exhalation pressure of 10 - 20 cm H_2O, to maintain a fixed flow rate of 50 ±5 ml/s. The instrument stops the measurement at pressures outside the interval. Warning alerts sounds at 10 - 12 and 18-20 cm H_2O.

11.11 Memory capacity

Up to 15, 000 measurements, depending on the size of the measurement files.

11.12 Patient filter

Disposable filter to be changed for each new measurement session and for each patient.
Bacterial, viral filter, CE marked according to Medical Device Directive Class I.

11.13 Bluetooth

NIOX VERO® has a Bluetooth class 2 receiver/transmitter with:

- Frequency band of 2402MHz~2480 MHz.
- Modulation method
  - 0,5BT Gaussian FIlter 2 FSK modulation index: 0.28~0.35 (Basic Rate 1Mbps)
- π/4-DQPSK (EDR 2Mbps)
- 8DPSK (EDR 3Mbps)
- ERP
  - Power class 2

11.13.1 R&TTE Directive

Hereby, Aerocrine AB, declares that this NIOX VERO is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

11.13.2 IC

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence.

L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Contains IC: 337L-MBH7BTZXXC2

11.13.3 FCC

FCC CAUTION

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

Properly shielded and grounded cables and connectors must be used for connection to host computers and / or peripherals in order to meet FCC emission limits.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Contains FCC ID: SQK-MBH7BTZXXC2

11.14 Rechargeable battery capacity

Only use the power adapter or USB cable supplied by Aerocrine to charge the battery.
Capacity: Approx. 30 measurements per day or 36 hours stand-by in 77°F environment condition.
Lifetime: At least one year with normal use.
Charging time: <8 hours under normal conditions.
Lowered capacity, and/or when 8 hours of charging time does not charge the battery fully, indicates that the battery should be replaced.
Battery Type No BJ-G510039AA, Article No 12-1150.

Note: *To charge the battery by USB cable, the instrument needs to be* ***powered off****.*

11.15 Instructions for transport and storage

CAUTION! Always use a closed bag or box for transportation and storage of NIOX VERO®.

1. Verify that the instrument is turned off and disconnected from the power supply.
2. Remove the patient filter and attach the protective cap on the handle.
3. Place the instrument and accessories in the bag and close bag.
4. Verify that the storage environment conditions are appropriate (see recommendations for NIOX VERO, including Sensor.

11.15.1 NIOX VERO®, including Sensor (transportation and storage)

- Relative humidity range: 20% to 80%, non condensing.
- Temperature range: 50 to 95 °F

- Atmospheric pressure range: 700 to 1060 hPa

When transporting the instrument from one location to another with different ambient conditions, a prolonged stabilization period might be required before measurements can be performed.

11.15.2 NIOX VERO® instrument (transport and storage in its unopened original package without Sensor)

- Relative humidity range: 10% to 90%, non condensing (maximum 1 week when outside relative humidity range 10% to 80%).
- Temperature range: -4°F to 140°F (maximum 1 week when outside temperature range 50°F to 95°F).
- Atmospheric pressure range: 500 to 1070 hPa

11.15.3 NIOX VERO® Sensor (transport and storage in original package)

- Relative humidity range: 10% to 99%, non condensing.
- Recommended temperature range: -4°F to 77°F (maximum 24h for the ranges -4°F to 41°F and 95°F to 140°F)
- Atmospheric pressure range: 700 to 1070 hPa

12 NIOX VERO® parts and accessories

CAUTION! When selecting an accessory for your NIOX VERO® product keep in mind that an accessory not recommended by Aerocrine may result in loss of performance, damage to your NIOX VERO product, fire, electric shock, injury or damage to other property. The product warranty does not cover product failure or damage resulting from use with non approved accessories. Aerocrine takes no responsibility for health and safety problems or other problems caused by the use of accessories not approved by Aerocrine.

12.1 Parts included in NIOX VERO® package (Article No. 12-1200)

NIOX VERO® Instrument (12-1000)

NIOX VERO® Breathing Handle (12-1010)

NIOX VERO® Handle Cap (12-1009)

NIOX VERO® Power Adapter (12-1120)

NIOX VERO® Power Cord (12-1230)

NIOX VERO® USB Cable (12-1002)

NIOX VERO® Battery (12-1150)

NIOX VERO® Stand (12-1001)

NIOX VERO® User Manual (EPM-000165)

NIOX® Panel USB Memory stick (12-1003)

12.2 Accessories

NIOX VERO® Test Kit 100 (12-1810)
Contains: 1 Sensor* for 100 tests and 100 NIOX VERO® Filters**

NIOX VERO® Test Kit 300 (12-1830)
Contains: 1 Sensor* for 300 tests and 300 NIOX VERO® Filters**

NIOX VERO® Test Kit 500 (12-1850)
Contains: 1 Sensor* for 500 tests and 500 NIOX VERO® Filters**

NIOX VERO® Test Kit 1000 (12-1900)
Contains: 1 Sensor* for 1000 tests and 1000 NIOX VERO® Filters**

* NIOX VERO® Sensor
Pre-calibrated disposable Sensor for 100, 300, 500 or 1000 measurements. Operational life-time: Maximum 12 months when installed in NIOX VERO® or expiration date as stated on the Sensor, whichever comes first.

** NIOX VERO® Filter Disposable filter to be changed for every patient. Bacterial, viral filter according to Medical Device Directive Class I.

NIOX Apps (12-1004)

13 Medical Device Reporting (MDR)

Aerocrine, as a medical device manufacturer, must have a Medical Device Reporting system in place to report to the FDA, any adverse events that have occurred with its medical products.The purpose of the Medical Device Reporting system is to ensure the health and safety of patients, users and others using medical products by reducing the likelihood of the same type of adverse event being repeated. This is achieved by immediate notification of experienced incidents to enable corrective and preventive actions.

Specific guidelines, Medical Device Reporting system for user facilities, are applicable for users of medical devices. An MDR reportable event is an event about which a user facility becomes aware of information that reasonable suggests that a device has or may have caused or contributed to a death or serious injury. Manufacturers of medical devices are obliged to report adverse incidents to the FDA. Any user of Aerocrine's products, who experience an adverse event related to the product, must therefore immediately report this to Aerocrine Inc. The report should contain the following:

- Description of the incident
- When and where did the incident occur?
- What product / accessory was involved, serial number/batch number?
- Was the incident related to instructions for use of the product?
- Was the risk foreseeable and clinically acceptable in view of potential patient benefit?
- Was the outcome adversely affected by a patient's pre-existing condition?
- Has the event been reported to the FDA? (only applicable if the use of the device has or may have caused or contributed to injury or death)

The report should be forwarded, by e-mail, fax or telephone, to:

Aerocrine Inc. 5151 McCrimmon Parkway, Suite 260, Morrisville, NC 27560, USA

Phone: +1 (866) 275-6469,

Fax: +1 (877) 329-6469

e-mail: service.us@aerocrine.com

14 Guidance and manufacturer's declaration - Electromagnetic immunity and electromagnetic emissions

14.0.1 Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity		
The NIOX VERO® is intended for use in the electromagnetic environment specified below. The customer or the user of the NIOX VERO® should assure that it is used in such an environment.		
Immunity test	Compliance	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	'+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should at least 30%.
Electrical fast transient/burst IEC 61000-4-4	'+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	'+/- 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NIOX VERO® requires continued operation during power mains interruptions, it is recommended that the NIOX VERO® be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: *U_T is the a.c. mains voltage prior to application of the test level.*		

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used not closer to any part of the NIOX VERO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3,5 / 3] X root (P) d = [3,5 / 3] X root (P) at 80 MHz to 800 MHz d = [7,0 / 3] X root (P) at 800 MHz to 2,5 GHz where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (**a), should be less than the compliance level in each frequency range (** b). Interference may occur in the vicinity of equipment marked with the following symbol:

Note: *At 80 MHz and 800 MHz, the higher frequency range applies.*

Note: *These guidelines may not apply in all situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitter, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NIOX VERO® is used exceeds the applicable RF compliance level above, the NIOX VERO® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NIOX VERO®.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should less than 3.0 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the NIOX VERO®

The NIOX VERO® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NIOX VERO® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NIOX VERO® as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz d = [3,5/3,0]x √P	80 MHz to 800 MHz d = [3,5/3,0]x √P	800 MHz to 2,5 GHz d = [3,5/3,0]x √P
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer

Note: *At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.*

Note: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

14.0.2 Electromagnetic emissions

<table>
<tr><td colspan="3">Guidance and manufacurer’s declaration - electromagnetic emissions</td></tr>
<tr><td colspan="3">The NIOX VERO® is intended for use in the electromagnetic environment specified below.
The customer or the user of the NIOX VERO® should assure that it is used in such an environment</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The NIOX VERO® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The NIOX VERO® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class D</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Information in this document is subject to change.

Amendments will be made available by Aerocrine AB as they occur.

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Based on the company's intellectual property, Aerocrine develops and commercializes products for the monitoring of nitric oxide (NO) as a marker of inflammation, to improve the management and care of patients with inflammatory disease in the airways.

Patents:

For information about patents relating to Aerocrine products see www.aerocrine.com

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